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PROGRAMME, THE ENVIRONMENT FUND AND ADMINISTRATIVE AND OTHER BUDGETARY MATTERS

Biosafety-related issues: implementation of Governing Council decision 19/16

Report of the Executive Director

Summary

The present document, submitted in accordance with Governing Council decision 19/16 of 7 February 1997, on biosafety, describes the relevant activities completed by the United Nations Environment Programme (UNEP). These included publication of UNEP International Technical Guidelines for Safety in Biotechnology; implementation of the "UNEP/GEF Pilot Biosafety Enabling Activity Project" with two components (support to 18 countries for the preparation of national biosafety frameworks and support to eight regional workshops on biosafety); operationalization of the International Register on Biosafety; and initiation of other biosafety-related activities.

Suggested action by the Governing Council

The Governing Council may wish to:

1. Note with satisfaction the report by the Executive Director on the implementation of its decision 19/16, on biosafety;

2. Request the Executive Director to develop multi-year regional biosafety programmes to support the review, update and implementation of the UNEP International Technical Guidelines for Safety in Biotechnology in view of rapid changes and developments in the field of modern biotechnology and in

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the context of the provisions and work programmes developed for implementation of the protocol on biosafety being developed under the Convention on Biological Diversity;

3. Request the Executive Director to continue mobilizing resources, including through the Global Environment Facility, for support to developing countries and countries with economies in transition to prepare effective national biosafety frameworks in the context of the UNEP International Technical Guidelines for Safety in Biotechnology as well as the protocol on biosafety to the Convention on Biological Diversity;

4. Request the Executive Director to continue promoting greater awareness and subregional/regional cooperation in the enhancement of capacities for exchange/supply of information on safety in biotechnology through maintaining and enhancing the International Register on Biosafety;

5. Note with appreciation the support provided from the Global Environment Facility to the Pilot Biosafety Enabling Activity Project and invite the Global Environment Facility to continue to provide support to developing countries and countries with economies in transition for capacity-building on issues related to biosafety, following the completion of the pilot project;

6. Request the Executive Director to support the establishment of subregional and regional biosafety focal points in collaboration with the Secretariat of the Convention on Biological Diversity and other relevant organizations, as a complement to the Biosafety Clearing-house.

I. INTRODUCTION

1. Recognizing that biotechnology can contribute substantively to the improvement of agriculture, fisheries, forestry, health care and environmental management, Governments represented at the United Nations Conference on Environment and Development, held in Rio de Janeiro in June 1992, undertook to consider international cooperation on biotechnology and relevant safety aspects in order to maximize the benefits associated with biotechnology while minimizing its potential risks. 1/ That commitment includes: sharing experience, capacity-building and international agreement on principles for safety.

2. Biotechnology and related biosafety aspects are also important features of the Convention Biological Diversity. One issue of particular concern in this context is the use and release of living modified organisms resulting from modern biotechnology that may have adverse impact on the conservation and sustainable use of biological diversity. Indeed, article 8(g) of the Convention provides that each contracting party shall, as far as possible and as appropriate, establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impact that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. In addition, article 19, paragraph 3, of the Convention provides that the parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. Furthermore, paragraph 4 of the same article states that each party is obliged directly, or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in article 19, paragraph 3, to provide any available information about the use and safety regulations required by that party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the party into which those organisms are to be introduced.

3. While the Conference of the Parties to the Convention was examining how to implement the article 19, paragraph 3, the Governing Council in its decision 18/36 affirmed the desirability of UNEP contributing to international efforts on biosafety, including through the development of International Technical Guidelines for Safety in Biotechnology, while avoiding duplication with the work of the other organizations, in particular the negotiation of a protocol on biosafety under the Conference of the Parties to the Convention on Biological Diversity.

1/ See chapter 16 of Agenda 21 (Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992, A/CONF.151/26/Rev.1 (Vol. I and Vol. I/Corr.1, Vol. II, Vol. III and Vol. III/Corr.1)) (United Nations publication, Sales No. E.93.I.8 and corrigenda), Vol. I: Resolutions Adopted by the Conference, resolution 1, annex II).

4. At its second meeting, held in Jakarta in November 1995, the Conference of the Parties to the Convention, through its decision II/5, stressed the importance of the urgent finalization of the UNEP International Technical Guidelines for Safety in Biotechnology and acknowledged that they could contribute to the development and implementation of a protocol on biosafety without prejudicing the development and conclusion of such a protocol. The Conference further noted that the Guidelines may be used as an interim mechanism during the development of national capacities to assess and manage risks, establish adequate information system and develop expert human resource in biotechnology.

5. The Guidelines were then developed through a series of seven regional and subregional workshops on the basis of common elements and principles derived from relevant national, regional and international instruments, regulations and guidelines. The UNEP International Technical Guidelines for safety in Biotechnology were adopted at a global consultation held in Cairo in December 1995. They are based on the premise that adequate mechanisms for risk management and capacity-building through, inter alia, the exchange of information and the use of the Guidelines at the national, regional and international levels can contribute significantly to safety in biotechnology.

6. At its third meeting, held in Buenos Aires in November 1996, the Conference of the Parties to the Convention welcomed the finalization and adoption of the UNEP Guidelines. Reiterating the view that they constitute a useful complement in the development and implementation of a protocol on biosafety, the Conference also requested the Global Environment Facility (GEF) to provide financial resources to developing country parties to the Convention for capacity-building in biosafety, including capacity-building for the implementation of the UNEP Guidelines. 2/

7. It is against this background that the Governing Council adopted its decision 19/16 of 7 February 1997, on biosafety. It is also in the light of the foregoing that a number of countries made requests to UNEP for scientific and technical support, including financial assistance through GEF, to enable them undertake capacity-building activities pertinent to the implementation of relevant aspects of article 8(g) of the Convention. The activities envisaged would entail the development of national biosafety frameworks to facilitate implementation of relevant international biosafety guidelines and/or any biosafety agreement(s) under the Convention on Biological Diversity.

8. Since a number of issues pertaining to biosafety are yet to be agreed upon in the protocol on biosafety currently under negotiation, it is not yet possible to have a full understanding of the kinds of assistance that countries might need towards addressing biosafety issues and future implementation of biosafety agreements. Following discussions between UNEP, the GEF secretariat, the United Nations Development Programme (UNDP), the World Bank, the Secretariat of the Convention on Biological Diversity and the GEF Scientific and Technical Advisory Panel (STAP), it was agreed that the use of an enabling activity framework to assist countries to first of all

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2/ See decisions III/9, para. 2 (a), and III/20 of the Conference of the Parties to the Convention on Biological Diversity, as contained in document UNEP/CBD/COP/3/38, annex II.

make a quick initial assessment of the state-of-play in the country concerned on matters of biosafety, accompanied by a global awareness enhancing initiative on biotechnology and related biosafety aspects, given the central importance of the these issues for the Convention and the potential longer-term operational implications for GEF, was the best way to proceed on the issue at the time.

9. Accordingly, at its meeting held from 4 to 6 November 1997, the GEF Council approved the UNEP/GEF Pilot Biosafety Enabling Activity Project, consisting of a national-level component (amounting to $1,797,000) and a global-level component (amounting to $765,000). In essence, the pilot project aims at providing GEF, the Conference of the Parties to the Convention, the Governing Council, countries, international organizations, non-governmental organizations and the private sector with a much clearer understanding and appreciation of the kinds of assistance countries might need towards addressing biosafety issues and future implementation of biosafety agreement(s) under the Convention on Biological Diversity, while recognizing that there is an urgent need to undertake awareness-raising programmes about: (i) the importance of biotechnology; and (ii) capacity-building requirements for safety in biotechnology and related biosafety issues.

10. In paragraph 6 (a) of its decision 19/16, the Governing Council requested the Executive Director, subject to the availability of financial resources, to continue to promote the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology, particularly in developing countries, by carrying out such activities at the international, subregional and regional levels developed in consultation with the involved parties and organizations.

II. ACHIEVEMENTS

A. Implementation of the Pilot Biosafety Enabling Activity Project

11. A number of national biosafety proposals and a medium-sized project proposal were formulated and submitted to GEF for support to developing countries and countries with economies in transition for the development of their national biosafety mechanisms, incorporating various biosafety activities at national level that would also facilitate the promotion of subregional, regional and global cooperation in key aspects of biosafety and biotechnology and the application of biotechnology products.

12. Three UNEP/GEF bilateral meetings were held, in March, June and September 1997, during which, among other things, 18 national biosafety proposals and a medium-sized global biosafety project proposal encompassing support to regional workshops on biosafety, were presented by UNEP to GEF for funding. Subsequently, the GEF Council, at its meeting held from 4 to 6 November 1997, considered and approved the proposals as a single package under the title "Pilot Biosafety Enabling Activity Project", for implementation over the period from April 1998 to March 1999. The pilot project consisted of two components, namely, a national-level component and a global-level component, as described below.

1. National-level component

13. The national-level component of the project, with funding in the amount of $1,797,000, provides for assistance for the preparation of national biosafety frameworks by the following 18 countries: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda and Zambia. The 18 participating countries vary in size, geographical location, level of socio-economic development and the stage of preparation of their national biodiversity strategies and action plans. Funding allocations concerning the subprojects took these attributes into consideration. Over a period of one year (April 1998-March 1999), the countries are embarking on various activities towards the preparation of their national biosafety frameworks using the UNEP International Technical Guidelines for Safety in Biotechnology as a guide.

2. Global-level component

14. The global-level component of the project, with funding in the amount of $765,000, provides support to regional workshops on biosafety. This component has been executed in collaboration with the Information Resource on the Release of Organisms into the Environment (IRRO). Under this component, two back-to-back regional workshops on biosafety were held in 1998 in each of the following regions: Latin America and the Caribbean (Havana, 26-30 October); Central and Eastern Europe (Bled, Slovenia, 11-15 November); Africa (Nairobi, 23-27 November); and Asia and the Pacific (New Delhi, India, 7-11 December).

15. The purpose of the regional workshops was to promote a greater awareness, understanding and appreciation of biosafety and biotechnology issues by countries, in particular developing countries and countries with economies in transition. The workshops promoted the exchange of views and information on biosafety by countries, organizations, the scientific community, relevant non-governmental organizations and the private sector (in particular the bio-industry). Their aim was to facilitate the preparation and implementation of effective national biosafety frameworks within the context of the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology and/or any future legal instrument(s) on biosafety, such as the protocol on biosafety currently under negotiation by the Open-ended Ad Hoc Working Group on Biosafety within the framework of the Convention on Biological Diversity.

16. The workshops provided a forum for the consideration of issues related to the assessment and management of risks associated with living modified organisms (LMOs)/organisms with novel traits (ONTs) resulting from biotechnology, including the assessment of their environmental impacts, with a view to improving biosafety. The workshops also focused on the issues related with transboundary transfer of LMOs, including appropriate mechanisms and modalities for the supply and exchange of information regarding biosafety. They also addressed issues pertinent to capacity-building requirements to enhance safety in biotechnology at the national, regional and global levels.

3. Outputs of the project

17. Outputs of the project will include reports of the regional workshops, as well as 18 country reports on national biosafety frameworks. In addition, a composite synthesis report encompassing the entire Pilot Biosafety Enabling Activity Project will be prepared.

B. Progress made in the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology

18. The UNEP International Technical Guidelines for Safety in Biotechnology, published in April 1996 in all the official languages of the United Nations, have been widely distributed to Governments, institutions and organizations, including non-governmental organizations and the biotechnology industry. They were also made available at relevant intergovernmental meetings held in 1996 including the first meeting of the Open-ended Ad Hoc Working Group on Biosafety, held in Aarhus, Denmark from 22 to 26 July 1996, the second meeting of the Subsidiary Body for Scientific, Technical and Technological Advice under the Convention on Biological Diversity, held in Montreal from 2 to 6 September 1996, and the third meeting of the Conference of the Parties to the Convention on Biological Diversity, held in Buenos Aires from 4 to 15 November 1996.

19. Progress made in the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology and related capacity-building requirements has been duly conveyed to the Governing Council at its nineteenth session, the Commission on Sustainable Development at its fifth session, the Conference of the Parties to the Convention on Biological Diversity at its third and fourth meetings and the Open-ended Ad Hoc Working Group on Biosafety at its fourth and fifth meetings.

20. In the margins of the fourth meeting of the Open-ended Ad Hoc Working Group on Biosafety, held in Montreal in February 1998, UNEP convened a workshop at which the details of the UNEP/GEF Pilot Biosafety Enabling Activity Project were presented and discussed. Delegates from the 18 countries participating in the project, as well as other participants, including those from non-governmental organizations and the private sector, attended the workshop.

21. Another workshop was staged during the fourth meeting of the Conference of the Parties to the Convention on Biological Diversity, held in Bratislava in May 1998. It offered participants an opportunity to exchange views on the practical aspects of the implementation of the national and regional components of the project.

22. Likewise, during the fifth meeting of the Open-ended Ad Hoc Working Group on Biosafety, a UNEP workshop was again held to brief the delegates on the UNEP/GEF project. The workshop was very well attended (over 200 people), and eight of the 18 countries participating in the project gave excellent presentation of progress made to date in their preparation of national biosafety frameworks under the national-level component.

23. In the light of the experience gained and lessons learned by countries, organizations and private sector (in particular bio-industry), in the application of the UNEP Guidelines, there will be a need for the review and update of the Guidelines, taking also into consideration the provisions of the eventual protocol on biosafety.

C. International Register on Biosafety

24. The International Register on Biosafety (IRB), launched in July 1996, has been placed on the Internet and can be located at the following address: http://www.unep.org/unep/program/natres/biodiv/irb/welcome.htm. The IRB serves as a mechanism for the implementation of the UNEP Guidelines for the purpose of exchange of specific information between biosafety focal points and the exchange of general information about national biosafety mechanisms, including information on biosafety guidelines, regulations, notification schemes and approvals given for the marketing of products of modern biotechnology, etc. The Register facilitates exchange of general information about generic research of value to risk assessment and risk management. The Register recognizes the need to avoid duplication and enhances synergy and complementarity through linkages with existing relevant databases such as the Biosafety Information Network and Advisory Services (BINAS) of the United Nations Industrial Development Organization (UNIDO) and BioTrack of the Organization for Economic Co-operation and Development (OECD), among others. Consultations were undertaken between UNEP and relevant organizations (including UNIDO and OECD) to enhance synergy and complementarity of the information contained in the international databases, including BINAS, BioTrack and BIOBIN (a cooperative resource on regulatory issues in biotechnology developed between OECD and UNIDO). A joint demonstration of the built-in interlinkages among the UNEP/OECD/UNIDO Web-sites was made during the fourth meeting of the Open-ended Ad Hoc Working Group on Biosafety. The Register was also featured during the regional workshops on biosafety as one of the global mechanisms and modalities for supply and exchange of biosafety information.

25. IRB could thus facilitate exchange of information on living modified organisms (LMOs)/genetically modified organisms (GMOs)/organisms with novel traits (ONTs), as well as information on subregional, regional and global activities on biosafety.

26. A list of over 100 national biosafety focal points has been posted on the Register, which is being updated, as appropriate, as and when more Governments and organizations submit the details of their focal points. The results of a UNEP survey on the implementation of the UNEP Guidelines conducted for presentation at the International Workshop to Follow up on the UNEP International Technical Guidelines for Safety in Biotechnology, held in Buenos Aires on 31 October and 1 November 1996, are also posted on the IRB Web-site. It contains biosafety information contributed by Governments in line with the UNEP Guidelines.

27. Pursuant to paragraph 6 (c) of Governing Council decision 19/16, it is proposed to hold the second international workshop on the state of the art of the implementation of the UNEP Guidelines in June/July 1999 after the adoption of the protocol on biosafety in Cartegena, Colombia, in February 1999. Such timing would allow the workshop to take into consideration the

results of the UNEP/GEF Pilot Biosafety Enabling Activity Project, the outcome of a workshop on biosafety regulatory capacity-building to be held in Mexico City from 13 to 15 January 1999, and the provisions of the protocol on biosafety.

III. OTHER BIOSAFETY ACTIVITIES

28. Pursuant to decision 19/16, the UNEP programme of work for the biennium 1998-1999 included the following biosafety/biotechnology activities, among others:

(a) Support for training, research, information exchange and pilot activities encompassing awareness-raising through trained personnel in biotechnology safety and environmentally sound biotechnology and inventorying of transferable environmentally sound biotechnology;

(b) Training in biotechnology safety and environmentally sound biotechnology, including the holding a regional symposium on agrotechnologies based on biological nitrogen fixation for desert agriculture, implemented by Environmental Studies and Research Unit (ESRU), Faculty of Agriculture, Cairo University;

(c) Support to Cairo Microbiological Resources Centre (MIRCEN) for training workshops on microbial biofertilizers and plant molecular biology and biotechnology;

(d) Training in taxonomy for ex situ and in situ conservation, which included the provision of support for regional training under the project entitled "Partnership in Capacity-building for Sustainable National Plant Genetic Resources Programmes", implemented by the International Plant Genetic Resources Institute (IPGRI);

(e) A UNEP/FAO project on information dissemination and training for technology transfer in domestic animal genetic resources".

29. At the end of the fifth meeting of the Open-ended Ad Hoc Working Group on Biosafety, held in Montreal from 17 to 28 August 1998, a study tour of sites of transgenic crops in the United States was arranged by the American Seed Trade Association (ASTA) on behalf of the bio-industry for the 18 countries participating in the UNEP/GEF pilot project. The study tour was undertaken by 14 countries over the period from 29 August to 5 September 1998.

IV. CONCLUSIONS AND RECOMMENDATIONS

30. Governing Council decision 19/16 on biosafety has been implemented to a very large extent in spite of financial constraints and the short period over which the UNEP/GEF Pilot Biosafety Enabling Activity Project had to be undertaken.

31. Both Agenda 21 and the Convention on Biological Diversity are now recognized as the principal vehicles and instruments for international cooperation with regard to issues of conservation and sustainable use of biological diversity, and the equitable sharing of benefits derived therefrom, including through the development and application of modern biotechnology. When a protocol on biosafety is concluded and adopted in Cartegena in February 1999, it will constitute another important instrument for international cooperation on issues related to biosafety.

32. Over the past five years since the Convention on Biological Diversity entered into force, UNEP has played a significant role at the global, regional and national levels through various complementary initiatives in support of the work of the Convention Secretariat and the Conference of the Parties, as well as the work of the Open-ended Ad Hoc Working Group on Biosafety, thus facilitating the implementation of the Convention. The development of the UNEP International Guidelines for Safety in Biotechnology, and activities under the UNEP/GEF Pilot Biosafety Enabling Activity Project are but a few examples.

33. The protocol on biosafety will be a vital vehicle through which international initiatives on biosafety can be focused and synergized at the national, subregional, regional and global levels, in respect of capacity-building efforts in the priority areas of prime importance for the effective implementation of articles 8(g) and 19, paragraph 4, of the Convention, as well as the provisions of the protocol.

34. Particular areas of capacity-building requiring international coordination and focus include: the development of national/subregional/regional capacities to assess and manage risks; establishment of adequate systems for supply and exchange of information on biosafety; and development of a critical mass of expert human resources in modern biotechnology, at the national, subregional and regional levels.

35. As an implementing agency of GEF, and in collaboration with UNDP, the World Bank and other partners, UNEP has a unique mandate and a significant as well as catalytic role to play in this regard. Through its programmes and the coordination of international initiatives on biosafety in support of environmentally sound development and application of biotechnology, and by mobilizing scientific, technical and other support, including financial resources through GEF, to developing countries and countries with economies in transition, it is envisaged that UNEP will undertake specific types of projects which are linked to UNEP's strategic role and areas of expertise, to respond to country needs as well as subregional and regional priorities for capacity-building requirements for safety in biotechnology.

36. The lack of a comprehensive assessment of the state of the art in safety in biotechnology at the global, regional and subregional levels was evident during regional workshops on biosafety and the preparation of national biosafety frameworks. There is a need for a comprehensive analytical assessment of existing biosafety regulations/guidelines and the status of safety in biotechnology globally. The assessment of the status of biosafety will contribute to increased regional and global cooperation and the achievement of the objectives of the Convention on Biological Diversity, and would provide an important tool for obtaining objectively assessed

information that may facilitate the work of the Subsidiary Body for Scientific, Technical and Technological Advice under the Convention on Biological Diversity in the area of biosafety, as well as the biosafety protocol process, through the proposed Intergovernmental Committee on the Biosafety Protocol (ICBP) and the Conference of the Parties. The results of this assessment should be made available through the same mechanism developed for the full Global Biodiversity Assessment report.

37. Following the completion of the Pilot Biosafety Enabling Activity Project and the adoption of the protocol on biosafety, there will be a need for countries to have in place national biosafety frameworks that will facilitate their implementation of the provisions of the protocol. Accordingly, GEF should be requested to provide financial support to additional countries to prepare their national biosafety frameworks or to undertake relevant capacity-building initiatives in the priority focal areas cited in paragraph 34 above.

38. There is also a need to establish subregional/regional biosafety focal points for the exchange and supply of expertise and information on issues related to safety in biotechnology.